NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ENDO PHARMACEUTICALS, INC., Plaintiff, v. IMPAX LABORATORIES, INC., Defendant.	Civil Action No.: 16-2526 (JLL) **OPINION**

LINARES, District Judge.

This matter comes before the Court by way of Defendant Impax Laboratories, Inc.'s Motion to Dismiss the Amended Complaint pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure (ECF No. 22). Plaintiff Endo Pharmaceuticals, Inc. has submitted an opposition (ECF No. 25), to which Defendant has replied to (ECF No. 26). The Court decides this matter without oral argument pursuant to Rule 78 of the Federal Rules of Civil Procedure. For the reasons set forth below, the Court grants in part and denies in part Defendant's Motion to Dismiss Plaintiff's Amended Complaint.

I. BACKGROUND[1]

A. The Parties

Plaintiff is a Delaware corporation that researches, develops, manufactures, and sells prescription pharmaceuticals which are used to treat various ailments, including pain. (*See* ECF

[1] This background is derived from Plaintiff's Amended Complaint, which the Court must accept as true at this stage of the proceedings. *See Alston v. Countrywide Fin. Corp.*, 585 F.3d 753, 758 (3d Cir. 2009).

No. 13 at ¶ 2 ("Compl.")). Defendant is a Delaware corporation who is in the business of researching, developing, manufacturing, and selling generic and brand-name prescription pharmaceuticals. Compl. at ¶ 3. In 2006, Plaintiff received U.S. Food and Drug Adminitration ("FDA") approval for its new extended-release pain reliever, OPANA® ER ("Original OPANA"), pursuant to patents issued in 1997 and 1999.[2] Compl. at ¶ 13. Shortly thereafter, Plaintiff began selling Original OPANA.

B. The Prior District of New Jersey Lawsuit

In June of 2007, Defendant submitted an Abbreviated New Drug Application ("ANDA") seeking FDA approval to sell generic versions of Original OPANA ("Generic Impax Tablets"). Compl. at ¶ 20-21. Thus, in 2008 Plaintiff instituted an action in the District of Delaware, which was later transferred to the District of New Jersey, alleging the Generic Impax Tablets would infringe on Plaintiff's Original OPANA Patents which were set to expire on September 9, 2013. ("Prior DNJ Action"). Compl. at ¶¶ 22 and 25. The parties settled the aforesaid litigation in June of 2010. Compl. at ¶ 23.

C. The Settlement Agreement

As a part of their settlement, the parties entered into a settlement and license agreement ("Agreement"). Compl. at ¶ 23; ECF No. 1-1. The Agreement permitted Defendant to sell its Generic Impax Tablets beginning on January 1, 2013 and required Defendant to pay a contingent royalty during a 180-day exclusivity period following the launch of the Generic Impax Tablets. Compl. at ¶ 26. However, at the time of settlement in June of 2010, Plaintiff had several patent

[2] At that time Plaintiff held to patents relating to Original OPANA bearing U.S. Patent Nos. 5,662,933 (" '933 Patent") and 5,958,456 (" '456 Patent") (collectively "Original OPANA Patents"). Original OPANA is an Oxymorphone Hydrochloride Extended-Release Tablet. Compl. at ¶¶ 13, 15-16. The active ingredient in Original OPANA is oxymorphone hydrochloride, which is an opioid subject to abuse. *Id.*

applications pending before the United States Patent and Trademark Office ("USPTO"), which covered Original OPANA and the Generic Impax tablets. These are the Patents in Suit herein and pertain to a tablet-hardening technology which was designed to prevent abuse by consumers. Compl. at ¶ 17. Plaintiff is the sole owner and assignee of the Patents in Suit. Compl. at ¶ 27. If granted, patent protection would be extended until at least the year 2023[3]. Plaintiff claims that it was considerably uncertain as to whether those patents would issue. *Id.*

During the course of negotiations to settle the Prior DNJ Action, Defendant repeatedly demanded that it be granted a license to future-issued patents relating to Original OPANA, including the Patents in Suit, if same were ever issued by the USPTO. Compl. at ¶ 28. Plaintiff initially refused to succumb to Defendant's request, as it had significant uncertainty regarding whether any of the pending patent applications would ever issue. Compl. at ¶ 30. Accordingly, the parties were at an impasse.

In order to facilitate consummation of the settlement, the parties entered into a compromise. Compl. at ¶ 32. Under the compromise, Plaintiff granted Defendant "a license to any patents issuing from the pending patent applications and other patents [Plaintiff] might acquire." *Id.*; *see also* Agreement § 4.1(a). Specifically, the Agreement granted defendant

> a non-tranferable …, non-sublicensable and royalty-free (except as set forth in Section 4.3) license …, under the Opana® ER Patents, any continuations, continuations in part, or divisionals thereof, and any patents and patent applications owned by [Plaintiff] … that cover or could potentially cover the manufacture, use, sale, offer for sale, importation, marketing or distributions of products (or any components thereof) that are the subject of [Defendant's ANDA] (the issued patents being "Existing Patents" and the patent

[3] The then-pending patent applications later were issued. U.S. Patent No. 8,309,122 (" '122 Patent") was issued on November 13, 2012; U.S. Patent No. 8,329,216 (" '216 Patent") was issued on December 11, 2012; and U.S. Patent No. 8,808,737 (" '737 Patent") was issued on August 19, 2014. (collectively "Patents in Suit"). Compl. at ¶¶ 30, 37-43.

> applications (and any patents issued thereunder) being the "Pending Applications" and the Existing Patents and Pending Applications being collectively the "Licensed Patents"), during the License Term, to make, have made, offer to sell, sell, have sold, market, distribute, import and use the Impax Products solely in or for the Territory.

Compl. at ¶ 34; *see also* Agreement § 4.1(a).

Additionally, the Agreement by the parties in 2010 included a provision that each party agreed to negotiate in good faith to amend the terms of said Agreement if and when a patent or patents issued from the pending patent applications. Compl. at ¶ 35. Section 4.1(d) of the Agreement states that the parties "agree[] to negotiate in good faith an amendment to the terms of the License to any patents which issue from any Pending Applications for the time period following the Exclusivity Period." Agreement § 4.1(d).

D. The Prior Southern District of New York Action

In February 2012, Plaintiff began manufacturing, marketing and selling its newly formulated crush-resistant version of OPANA ("OPANA CRF"). Compl. at ¶ 19. As of May 2012, Plaintiff was only selling its OPANA CRF tablets, not Original OPANA. *Id.* Defendant, also desiring to sell a generic version of OPANA CRF, filed an ANDA with the FDA seeking approval for same ("Impax CRF Tablet"). Compl. at ¶ 45.

As a result, Plaintiff instituted an action against Defendant, among other generic drug companies, in the Southern District of New York claiming that each of Defendant's generic versions of Original OPANA and OPANA CRF would infringe on the '122 Patent and the '216 Patent ("SDNY Action"). Compl. at ¶ 46. The SDNY Action went to trial on August 14, 2015. The Honorable Thomas P. Griesa, U.S.D.J. upheld the validity of the '122 and '216 Patents, and held that Defendant's Impax CRF Tablets did in fact infringe on claims 2, 3, 19, and 20 of the '122

Patent, and claims 1, 22, 50, 54, 57, 62, 64, and 71 of the '216 Patent. Compl. at ¶ 47-48. Therefore, Judge Griesa issued an injunction against Defendant prohibiting it from any future commercial manufacture or sale of its Impax CRF Tablet. Compl. at ¶ 47.

E. The Prior District of Delaware Action

As discussed, the '737 Patent was issued on August 19, 2014. Compl. at ¶ 42. Plaintiff further claims that Defendant "has had knowledge of the '737 [P]atent since no later than November 7, 2014," which is the date Plaintiff instituted a separate action in the District of Delaware ("Prior DE Action"). Compl. at ¶ 99. There, Plaintiff alleged that Defendant Generic Impax Tablet and the filing of the ANDA for its Impax CRF Tablet infringed upon its '737 Patent. Compl. at ¶ 101. However, on November 17, 2015, the Court issued an Opinion wherein it held "that the claims of the '737 [P]atent are invalid on the grounds that they are directed to unpatentable subject matter." Compl. ¶ 103. "No final judgment has been entered" in the Prior DE Action and Plaintiff plans on challenging the ruling. *Id.*

F. Pertinent Facts

As contemplated by the Agreement, Defendant began selling its generic version of Original OPANA in January of 2013. Compl. at ¶ 44. Also, as discussed, Defendant had also developed its hardened generic version, Impax CRF Tablet. Compl. at ¶ 45. Thus, on or about October 1, 2015, Plaintiff approached Defendant seeking to negotiate an amendment to Defendant's License as it pertained to the, Generic Impax Tablet, the Impax CRF Tablet and the Patents in Suit, pursuant to Section 4.1(d) of the Agreement. Compl. at ¶ 51. Plaintiff provided Defendant with a term sheet that contained "customary license terms" for the Patents in Suit, including a royalty for Defendant's allegedly infringing sales during the post-Exclusivity Period. Compl. at ¶¶ 51, 53.

Defendant reportedly refused to respond to this term sheet and rejected Plaintiff's request for a meeting. Compl. at ¶ 54.

Defendant took the position that it was not under the obligation to pay any royalties for the Patents in Suit because these patents were encompassed by the Agreement which granted Defendant a royalty-free license to same. Compl. at ¶¶ 54, 56. Further, Defendant advised Plaintiff that they only way it would be willing to negotiate for a payment of a royalty would be if Plaintiff expanded the license. *Id.* On or about April 19, 2016, Plaintiff advised Defendant that its actions in refusing to negotiate and attempting to expand the license to encompass the Patents in Suit were inconsistent with Section 4.1(d) of the agreement. Compl. at ¶ 57. Defendant did not respond. Compl. at ¶ 58.

Accordingly, Plaintiff brought this action for breach of contract (Count I), breach of the covenant of good faith and fair dealing (Count II), infringement of the '122, '216, and '737 Patents (Counts III-V), and unjust enrichment (Count VI). Defendant now moves to dismiss Plaintiff's Amended Complaint arguing it fails to state a claim up which relief can be granted. (ECF No. 22-1 ("Def. Mov. Br.")).

II. LEGAL STANDARD

To withstand a motion to dismiss for failure to state a claim, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 556). "The plausibility standard is not akin to

a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.*

To determine the sufficiency of a complaint under *Twombly* and *Iqbal* in the Third Circuit, the court must take three steps: first, the court must take note of the elements a plaintiff must plead to state a claim; second, the court should identify allegations that, because they are no more than conclusions, are not entitled to the assumption of truth; finally, where there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief. *See Connelly v. Lane Const. Corp.*, 809 F.3d 780, 787 (3d Cir. 2016) (citations omitted). "In deciding a Rule 12(b)(6) motion, a court must consider only the complaint, exhibits attached to the complaint, matters of public record, as well as undisputedly authentic documents if the complainant's claims are based upon these documents." *Mayer v. Belichick*, 605 F.3d 223, 230 (3d Cir. 2010).

III. ANALYSIS

Plaintiff's amended complaint alleges six causes of action: 1) breach of contract; 2) breach of the implied covenant of good faith and fair dealing; 3) infringement of the '122 Patent; 4) infringement of the '216 Patent; 5) infringement of the '737 Patent; and 6) unjust enrichment. The Court discusses each cause of action separately.

A. Breach of Contract

To survive dismissal of a breach of contract claim under New Jersey law,[4] a plaintiff must allege "(1) the existence of a valid contract between the parties; (2) failure of the defendant to perform its obligations under the contract; and (3) a causal relationship between the breach and the

[4] The Court applies New Jersey law pursuant to Section 8.4 of the Agreement.

plaintiffs alleged damages." *Sheet Metal Workers Int'l Ass'n Local Union No. 27, AFL–CIO v. E.P. Donnelly, Inc.*, 737 F.3d 879, 900 (3d Cir.2013) (citing *Coyle v. Englander's*, 199 N.J. Super. 212 (N.J. Super. Ct. App. Div. 1985)).

In this matter, the Court finds that Plaintiff has pled a *prima facie* cause of action for breach of contract. Indeed, Plaintiff has alleged that a contract existed between the parties, as well as the circumstances surrounding the creation of the contract. *See* Compl. at ¶¶ 23, 27-36. Specifically, Plaintiff alleges that the parties sought to settle the Prior DNJ Action and made various compromises to consummate said settlement. *Id.* The settlement was reduced to writing in the form of the Agreement, which both parties signed. *Id.*; *see also* ECF No. 13-1.

Plaintiff further alleges that Defendant breached the contract by failing to negotiate in good faith, pursuant to § 4.1(d) of the Agreement. Compl. at ¶ 66. Furthermore, Plaintiff alleges Defendant's refusal to negotiate was in bad faith. Compl. at ¶ 37. Finally, Plaintiff claims that it has been damaged by Defendant's breach of the Agreement. Compl. at ¶ 69. Accordingly, Plaintiff's Amended Complaint contains all the necessary factual allegations to plead a *prima facie* claim for breach of contract and survive Defendant's Motion to Dismiss. Moreover, Defendant's arguments regarding its "royalty-free license" and parol evidence are inapplicable at this stage of the litigation. Def. Mov. Br. at 10-17. Thus, Defendant's Motion to Dismiss is denied with respect to Count I of the Amended Complaint (Breach of Contract).

B. Breach of the Implied Covenant of Good Faith and Fair Dealing

The covenant of good faith and fair dealing is implicit in all contracts in New Jersey. *Pepe v. Riva Co.*, 85 F. Supp .2d 349, 390 (D.N.J. 1999). Under New Jersey law, all contracts include an implied covenant that the parties to the contract will act in good faith. *Gehringer v. Atl. Detroit*

Die sel Allison, LLC, 2009 U.S. Dist. LEXIS 23579, at * 31 (D.N.J. Mar. 23, 2009); *see also*, *e.g.*, *Sons of Thunder, Inc. v. Borden, Inc.*, 148 N.J. 396 (N.J. Sup. Ct. 1997). The covenant "mandates that 'neither party shall do anything which will have the effect of destroying or injuring the right of the other party to receive the fruits of the contract.'" *Seidenberg v. Summit Bank*, 348 N.J. Super. 243, 254 (N.J. Super. Ct. App. Div. 2002) (quoting *Sons of Thunder, supra* at 420).

Pursuant to Rule 8(d)(2) of the Federal Rules of Civil Procedure, a party "may set out 2 or more statements of a claim or defense alternatively or hypothetically, either in a single count or defense or in separate ones. If a part makes alternative statements, the pleading is sufficient if any one of them is sufficient." Fed. R. Civ. P. 8(d)(2); *see also Verizon N.J., Inc. v. Ntegrity Telecontent Servs., inc.*, 219 F. Supp. 2d 616, 635 (D.N.J. 2002).

Plaintiff in this action has successfully pled an alternate *prima facie* cause of action for breach of the implied covenant of good faith and fair dealing. As discussed, Plaintiff has alleged a contract existed between the parties. Plaintiff further alleges Defendant breached the implied covenant of good faith and fair dealing by refusing "to negotiate an amendment to the License for its [Generic Impax Tablets] under the [Patents in Suit] for additional products never contemplated or discussed by the parties at the time they entered into the [Agreement]." Compl. at ¶ 75. Additionally, Plaintiff claims Defendant's actions in connection with the negotiation and in response to this lawsuit were in bad faith and designed to circumvent Plaintiff's rights under the Agreement. Hence, Plaintiff's claim for breach of the implied covenant of good faith and fair dealing is sufficient to overcome Defendant's Motion to Dismiss Count II of the Amended Complaint.

C. Infringement of the '122, '216, and 737 Patents

Form 18 in the Appendix of the Federal Rules of Civil Procedure, sets forth a sample complaint for direct patent infringement. As explained by the Federal Circuit, "Form 18 requires: (1) an allegation of jurisdiction; (2) a statement that the plaintiff owns the patent; (3) a statement that defendant has been infringing the patent 'by making, selling, and using [the device] embodying the patent'; (4) a statement that the plaintiff has given the defendant notice of its infringement; and (5) a demand for an injunction and damages." *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1334 (Fed. Cir. 2012)(internal citations omitted). "The sample complaint in the Appendix of Forms is relevant because Federal Rule of Civil Procedure 84 states that 'the forms in the Appendix suffice under these rules and illustrate the simplicity and brevity that these rules contemplate.'" *Id.* (quoting Fed. R. Civ. P. 84). As such, a direct infringement claim is sufficient "[a]s long as the complaint in question contains sufficient factual allegations to meet the requirements of Form 18." *Id.* at 1336.

i. The '122 and '216 Patents

At this stage, the Court is satisfied that Plaintiff has sufficiently alleged direct infringement claims against Defendant with regards to the '122 and '216 Patents. Plaintiff has made sufficient allegations of jurisdiction. Additionally, Plaintiff has made the necessary allegations of ownership of the '122 and '216 Patents. Compl. at ¶¶38-41. Plaintiff has alleged Defendant has infringed on the '122 and '216 Patents by filing an ANDA for its Impax CRF Tablets. Compl. at ¶¶ 83 and 92. Furthermore, Plaintiff claims Defendant "continues to sell, and intends to continue to make, use, and sell, its infringing [Generic Impax Tablets] in the United States," and therefore asserts

Defendant's actions are willful infringements upon its '122 and '216 Patents. Compl. at ¶¶ 85, 86-87, and 94-95. Finally, Plaintiff alleges that Defendant's Generic Impax Tablets infringe upon the '122 and '216 Patents "for the same reasons and in the same way that Judge Griesa found in the [Prior SDNY Action]." Compl. at ¶¶ 84 and 93. Therefore, Plaintiff's claim for infringement on the '122 and '216 Patents is sufficient to overcome Defendant's Motion to Dismiss Counts III and IV of the Amended Complaint.

ii. The '737 Patent

The Court must grant Defendant's Motion to Dismiss Count V of the Amended Complaint. Whenever "the claims of a patent are held invalid in a suit involving one alleged infringer, an unrelated party who is sued for infringement of those claims may reap the benefit of the invalidity decision under the principles of collaterally estoppel." *Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 170 F.3d 1373, 1379 (Fed. Cir. 1999). The doctrine of collateral estoppel precludes a party from relitigating particular issues when "(1) the identical issue was previously adjudicated; (2) the issue was actually litigated; (3) the previous determination was necessary to the decision; and (4) the party being precluded from litigating was fully represented in the prior action." *Jean Alexander Cosmestics, Inc. v. L'Oreal USA, Inc.*, 458 F.3d 244, 249 (3d Cir. 2006).

Accordingly, collateral estoppel requires dismissal of Plaintiff's count for infringement upon its '737 Patent. In Count V, Plaintiff claims Defendant infringed upon its '737 Patent for essentially the same reasons it claims Defendant infringed on the '122 and '216 Patents. Compl. at ¶¶ 98-108. However, Count V fails because the '737 Patent has been held invalid in the Prior DE Action. *See* Def. Mov. Br. at 34.

First, Plaintiff concedes that the Prior DE Action involved an issue that is identical to a defense that will be asserted in this action; specifically, the validity of the '737 Patent. Compl. at ¶ 103; *see also Endo Pharmaceuticals, Inc., et al. v. Actavis, Inc., et al.*, No. 14-1381 (RGA) (D. Del. Nov. 17, 2015). The issue was actually litigated and fully briefed by the parties. Def. Mov. Br. at 36. The Magistrate Judge reviewed the submissions and issued a report and recommendation which was ultimately adopted "by the District Court Judge over [Plaintiff's] objections." *Id.* Accordingly, Defendant correctly notes that Plaintiff "had a full and fair opportunity to litigate the validity of the '737 patent before a District Court," where it did not succeed. *Id.*

Additionally, the decision to invalidate the '737 Patent was necessary to the decision in the Prior DE Action. *See Actavis*, *supra.* Finally, Plaintiff was fully represented in the Prior DE Action as it was a party to the matter and submitted objections and oppositions to the invalidation of the '737 Patent. Thus, the doctrine of collateral estoppel precludes Count V herein and it must be dismissed. The dismissal is without prejudice and subject to reinstatement should the '737 Patent later be found valid.

D. Unjust Enrichment

"The doctrine of unjust enrichment rests on the principle that a person shall not be allowed to enrich himself unjustly at the expense of another." *Assocs. Commercial Corp. v. Wallia*, 211 N.J.Super. 231, 243 (N.J. Super. App. Div. 1986)(citing *Callano v. Oakwood Park Homes Corp.*, 91 N.J.Super. 105, 108 (N.J. Super. App. Div.1966)). "A cause of action for unjust enrichment requires proof that 'defendant received a benefit and that retention of that benefit without payment would be unjust.'" *County of Essex v. First Union Nat. Bank*, 373 N.J. Super. 543, 549–50 (N.J.

Super. App. Div. 2004)(quoting *VRG Corp. v. GKN Realty Corp.*, 135 N.J. 539, 554 (N.J. Sup. Ct. 1994)), aff'd, remanded by 186 N.J. 46 (N.J. Sup. Ct. 2006).

To assert a *prima facie* cause of action for unjust enrichment a plaintiff must allege that: "(1) at plaintiff's expense (2) defendant received a benefit (3) under circumstances that would make it unjust for defendant to retain the benefit without paying for it." *In re K-DUr*, 338 F. Supp. 2d 517, 544 (D.N.J. 2004)(citing Restatement of Restitution § 1 (1937)); *see also VRG Corp*, *supra* at 554 (stating that a plaintiff seeking to assert a claim for unjust enrichment must establish that "defendant received a benefit[,] and that retention of that benefit without payment would be unjust[,] … [and plaintiff] expected remuneration from the defendant at the time it performed or conferred a benefit on defendant and that the failure of remuneration enriched defendant beyond its contractual rights.").

The Court finds that Plaintiff has pled an alternate *prima facie* cause of action for unjust enrichment. Preliminarily, as discussed above, Plaintiff may plead alternative theories of liability under Rule 8(d)(2) of the Federal Rules of Civil Procedure. Therefore, Defendant's argument that Count VI must be dismissed as duplicative fails. Next, the Complaint contains sufficient factual allegations to support a claim for unjust enrichment.

Specifically, Plaintiff alleges that is has expended significant costs and resources in obtaining the Patents in Suit and developing OPANA CRF. Compl. at ¶ 108. Furthermore, Plaintiff alleges that by permitting Defendant to manufacture and sell its Generic Impax Tablets, Defendant is receiving a benefit at Plaintiff's expense. Compl. at ¶¶ 109-11. Finally, Plaintiff claims that permitting Defendant to retain this benefit without payment to Plaintiff would be

unjust. *Id.* Thus, Defendant's Motion to Dismiss Count VI of the Amended Complaint is denied as Plaintiff has sufficiently pled a cause of action for unjust enrichment.

CONCLUSION

For the aforementioned reasons, Defendant's Motion to Dismiss Count I (Breach of Contract, Count II (Breach of the Implied Covenant of Good Faith and Fair Dealing), Count III (Infringement on the '122 Patent), Count IV (Infringement on the '216 Patent), and Count VI (Unjust Enrichment) is hereby denied. Defendant's Motion to Dismiss Count V (Infringement on the '737 Patent) is hereby granted. Count V is dismissed without prejudice and subject to reinstatement should the '737 Patent be held valid at a later time.

DATED: October 25, 2016

JOSE L. LINARES
UNITED STATES DISTRICT JUDGE